NO BREACH OF THE CODE

CASE AUTH/3453/1/21

ANONYMOUS v PFIZER

Conduct of a representative

An anonymous, non-contactable complainant who described him/herself as a concerned doctor, complained on behalf of his/her gastroenterology team about a named Pfizer Limited representative and his/her promotion of Xeljanz (tofacitinib).

Xeljanz was indicated, among other things, for the treatment of certain adult patients with moderately to severely active ulcerative colitis (UC).

The complainant alleged that the representative had called on the team and emailed and telephoned them using different names to try and secure appointments at a time when he/she had been advised that, because of concerns over Covid-19, the team did not want to see representatives.

The complainant also alleged that the representative had promoted his/her product outside of the licensed indication and had stated that this would help patients with Covid-19 and irritable bowel disease, by keeping them out of hospital. The team currently did not know of any data that tofacitinib was effective in those patients over and above the team's standard of care.

The complainant also stated that there had been a loss of trust as the representative had asked the team to consider writing up case studies without patient consent.

The detailed response from Pfizer is given below.

The Panel noted that the complainant had provided the name of the representative but insufficient information so that the particular circumstances could be clearly identified. The Panel noted that the parties' accounts differed.

The Panel noted Pfizer's submission that the named representative strongly denied the allegations of over contacting, using different names or disrespecting the wishes of any health professional, department or organisation on his/her territory and its investigation of the named representative's activities had found no evidence of such. The Panel noted that Pfizer had identified two health organisations that had requested no industry contact and that there was no record of the named representative having had any calls or contacts with them during the pandemic. Further, it had not received a 'banning order' from any health organisation or Trust as suggested by the complainant.

The Panel noted Pfizer's submission that the named representative denied discussing data for tofacitinib in patients with Covid-19 infection with any health professionals and that it had found no evidence that the representative had promoted a Pfizer medicine

outside its authorised indications or that he/she had made inaccurate, misleading or unsubstantiated claims about the medicine's use in patients with Covid-19.

The Panel noted that Pfizer stated it had ensured that throughout the pandemic, its representatives had received relevant, detailed, certified briefings on both the specific medicines that they promoted as well as on the wider health professional engagement framework that should be applied. Based on the evidence before it, the Panel did not consider that Pfizer's briefings advocated any course of action which would be likely to lead to a breach of the Code in relation to calls and contacts with health professionals and other relevant decision makers, nor with regard to the promotion of tofacitinib.

The Panel further noted Pfizer's submission that the representative denied having asked any clinical team to consider writing up case studies without patient consent, and that it had not instructed or briefed representatives to do so.

A judgement had to be made on the available evidence bearing in mind the extreme dissatisfaction usually necessary on the part of an individual before he or she was moved to actually submit a complaint and that the Panel could not contact the complainant for more information. The Panel further noted that the complainant bore the burden of proof and did not consider that he/she had established his/her case on the balance of probabilities. The Panel therefore ruled no breaches of the Code.

An anonymous non-contactable complainant, who described him/herself as a concerned doctor, complained on behalf of his/her gastroenterology team about a named Pfizer Limited representative and his/her promotion of Xeljanz (tofacitinib).

Xeljanz was indicated, among other things, for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a biologic agent.

COMPLAINT

The complainant alleged that the representative had called on the team at the hospital at a time when he/she had been advised that, because of concerns over Covid-19, the team did not want to see representatives. The representative had emailed and telephoned the team and used different names to try and secure appointments.

The complainant also alleged that the representative had promoted his/her product outside of the licensed indication. The representative had stated that this would help patients with Covid-19 and irritable bowel disease, by keeping them out of hospital. The team was concerned that this indicated that there was data to suggest that tofacitinib was effective in those patients over and above the team's standard of care. The complainant stated that the team currently did not know of any such data.

The complainant also stated that there had been a loss of trust as the representative had asked the team to consider writing up case studies without patient consent.

The complainant stated that the team had always had a long and respectful relationship with Pfizer and its medical team. The complainant asked for the matter to be investigated and that Pfizer train its representatives in being respectful and working with integrity.

The complainant stated that the team would issue a banning letter to Pfizer once its legal team was back after the holiday period. The complainant understood that one representative did not represent the entire company or the industry, however, since Covid had started the team had had examples of excellent representatives that had helped the team and worked with them from many different companies.

When writing to Pfizer, the Authority asked it to consider the requirements of Clauses 3.2, 7.2, 7.4, 9.1, 15.2, 15.4 and 15.9 of the Code.

RESPONSE

Pfizer stated that it took its commitment to working within the framework of the Code very seriously and was extremely concerned by the allegations associated with this complaint. Given the serious nature of the allegations, Pfizer took immediate action to withdraw the colleague from customer facing activity whilst a formal human resources investigation was conducted.

By way of background information on field force activity during the Covid-19 pandemic, Pfizer explained that in March 2020, in response to the national lockdown and rising pressures on the NHS, it decided to limit all customer engagement to reactive, virtual interactions only. That position was maintained for the duration of the first wave of the pandemic. On 20 May 2020, representatives were briefed that they could now resume proactive outreach via email and telephone, to customers with whom they had an ongoing relationship, to enquire about the possibility of a virtual interaction. Guidance was provided on the appropriate non-promotional content for outreach emails and telephone calls as well as instructions on the requirement to record the sending of such emails and any associated responses as 'touchpoint calls' in the Pfizer call recording system. This was intended to enable colleagues to carefully monitor and co-ordinate any customer outreach to ensure that it did not cause inconvenience and that any customer requests to suspend contact were observed and shared across the organisation. That guidance was updated on 22 July 2020 to allow colleagues to expand their outreach to other customers with whom they did not have an established relationship (copy of guidance provided). The requirement for interactions to be virtual remained and this was still Pfizer's policy at the time of writing this response in March 2021. Pfizer noted that in all of the briefings and guidance issued to colleagues, the need to be sensitive and respectful of the potential pressures on health professionals' time was clearly stated. This included limiting the number of times a representative could try to contact a particular health professional if no response was received. Pfizer considered that the framework that it had put in place for customer engagement throughout the pandemic had maintained the high standards expected of the industry.

Pfizer submitted that the representative identified by the complainant was experienced and respected, with an exemplary record. He/she had passed the ABPI representative exam with a distinction and passed the Pfizer therapy area and brand training assessments with scores of 90% and 88% respectively. The representative's line managers, territory colleague and aligned marketing colleague were interviewed as part of the in-house investigation and they all identified the representative as respectful, conscientious and diligent in applying the Code and Pfizer requirements relating to customer engagement. At interview, the representative demonstrated a clear understanding and accurate recall of the details of the Covid-19 health professional engagement briefings and strongly denied the allegations of over contacting, using different names or disrespecting the wishes of any health professional, department or organisation on his/her territory.

Analysis of the Pfizer call recording system indicated that between 5 June 2020 and 22 January 2021 the representative had sent three emails to one single health professional on his/her territory. The colleague had sent two emails each to a further 27 health professionals and all other health professionals contacted by email had only received one email during that period. No evidence of excessive or inappropriate patterns of email use were identified during the investigation.

A review of the representative's mobile telephone bills covering the period of February 2020 to December 2020 showed a reduction in the number of calls made in March, April and May 2020 which suggested that the representative had limited activity to reactive engagement only as was the Pfizer guidance at that time. The majority of calls listed on the telephone bill were to other mobile numbers which included Pfizer colleagues and personal calls. In the absence of specific telephone numbers to search for, related to the complaint, it was not possible to fully analyse the call records, however, no unusual patterns or volumes of calls were observed that raised any concerns for the investigating team.

Analysis of the representative's calls and contacts documented in the Pfizer call recording system indicated that he/she had conducted 34 remote calls across seven organisations, from the end of March 2020 to the end of January 2021. During that time, the representative also delivered six virtual meetings. Five of the meetings were representative promotional meetings each held with a different organisation. The sixth meeting was a speaker meeting which drew 16 attendees from six different organisations. This level of activity was in line with the levels delivered by other Pfizer colleagues and no unusual patterns of activity were identified.

During the interview process, two health organisations were identified that had requested no industry contact. Review of the Pfizer call recording system confirmed that no emails, telephone calls, appointments or meetings had been recorded against those organisations during the pandemic by the representative in question. That provided good evidence that the representative had appropriately respected and adhered to the wishes of individuals and the arrangements in force at organisations on his/her territory where those became apparent during the pandemic period.

Through the detailed human resources investigation of the representative's activities during the pandemic period, no evidence was found of any inappropriate levels of contact, use of different names or disregard for individual or organisations' wishes. Based on the available evidence, Pfizer denied a breach of Clause 15.4 of the Code.

With regard to Clauses 3.2, 7.2 and 7.4, Pfizer stated that its representatives received comprehensive training on the details of the summary of product characteristics (SPC) for the medicines that they promoted (copy provided). During the interview, the representative was clearly aware that the promotion of a medicine must be in accordance with the terms of its marketing authorisation. He/she had achieved a score over 85% in the brand training assessment, with approximately 50% of the examination questions being focused on the SPC. That indicated good knowledge and recall of the details of the SPC. The representative knew of no data for the medicine in patients with Covid-19 infection and he/she denied ever discussing the topic with any health professionals. The representative clearly recognised that as a topic that would be considered off-licence promotion and he/she accurately described the process for referring off-licence queries to the medical department.

Pfizer stated that its investigations had found no evidence that the representative had promoted a Pfizer medicine outside its authorised indications or that he/she had made inaccurate,

misleading or unsubstantiated claims about the medicine's use in patients with Covid-19. Pfizer therefore denied breaches of Clauses 3.2, 7.2 and 7.4.

In addition to the comprehensive activity briefings described above, in April 2020, the Pfizer inflammation team was provided with a Covid-19 pandemic specific briefing (copy provided). That briefing was designed to support colleagues with managing any questions related to use of the company's anti-inflammatory portfolio and risk of Covid-19 infection. That briefing clearly stated that 'currently there is no published data available on Pfizer's medicines as it relates to Covid-19 and whether Pfizer's products put patients at a greater risk of infection with Covid-19'. In addition, the briefing highlighted that 'It's important to know that the labelling for Xeljanz, Inflectra and Enbrel clearly communicate that patients have a risk of developing serious and potentially fatal infections, including viral infections. It is important to refer to the individual product labels for additional information'.

Pfizer stated that it had ensured that throughout the pandemic, its representatives had received relevant, detailed, certified briefings on both the specific medicines that they promoted as well as on the wider health professional engagement framework that should be applied. Pfizer considered that its actions met the requirements of Clause 15.9 and it denied any associated breaches.

Pfizer stated that it had not instructed or briefed representatives to either encourage health professionals to write up patient case studies or to collect patient case studies without patient consent or otherwise. That would not be within the remit of a Pfizer hospital representative's role. Both the representative in question and his/her line manager confirmed during interview that they had not received any such briefing or instruction. The representative spontaneously identified that this was not within his/her remit and strongly denied that he/she had ever asked any clinical team to consider writing up case studies without patient consent.

Pfizer submitted that throughout the pandemic it had been sensitive and respectful of the unprecedented pressures experienced by the NHS. At each stage of the pandemic Pfizer had fully briefed its representatives on the appropriate approach to engage with health professionals at that point in time. The framework and guidance developed was specifically designed to ensure that company activities would not cause inconvenience to the NHS in any way. Where Pfizer identified that there was a risk of health professionals potentially asking questions on the unlicensed use of its medicines in relation to Covid-19, it had proactively equipped its representatives with appropriate briefings. Pfizer believed this demonstrated that it had maintained the high standards expected of the industry and it denied a breach of Clause 9.1.

Pfizer stated that the rigorous human resources investigation had not identified any evidence of inappropriate conduct by the representative in question. Pfizer had not received a 'banning order' from any health organisation or trust as suggested by the complainant. Given that the complainant was non-contactable, it had not been possible to obtain further details of the alleged breaches of the Code and so based upon the findings of the human resources investigation, Pfizer considered that the representative had maintained a high standard of ethical conduct in the discharge of his/her duties and had complied with all relevant requirements of the Code. Pfizer thus denied a breach of Clause 15.2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other

complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant had provided the name of the representative but insufficient information so that the particular circumstances could be clearly identified. The Panel noted that the parties' accounts differed and noted the difficulty in dealing with complaints based on one party's word against the other; it was impossible in such circumstances to determine precisely what had happened.

The Panel noted Pfizer's submission that the named representative strongly denied the allegations of over contacting, using different names or disrespecting the wishes of any health professional, department or organisation on his/her territory and its investigation of the named representative's activities had found no evidence of such. The Panel noted that Pfizer had identified two health organisations who had requested no industry contact and that there was no record of the named representative having had any calls or contacts with them during the pandemic. Further, it had not received a 'banning order' from any health organisation or Trust as suggested by the complainant.

The Panel noted Pfizer's submission that the named representative denied discussing data for tofacitinib in patients with Covid-19 infection with any health professionals and that it had found no evidence that the representative had promoted a Pfizer medicine outside its authorised indications or that he/she had made inaccurate, misleading or unsubstantiated claims about the medicine's use in patients with Covid-19.

The Panel noted that Pfizer stated it had ensured that throughout the pandemic, its representatives had received relevant, detailed, certified briefings on both the specific medicines that they promoted as well as on the wider health professional engagement framework that should be applied. Based on the evidence before it, the Panel did not consider that Pfizer's briefings advocated any course of action which would be likely to lead to a breach of the Code in relation to calls and contacts with health professionals and other relevant decision makers, nor with regard to the promotion of tofacitinib.

The Panel further noted Pfizer's submission that the representative denied having asked any clinical team to consider writing up case studies without patient consent, and that it had not instructed or briefed representatives to do so.

A judgement had to be made on the available evidence bearing in mind the extreme dissatisfaction usually necessary on the part of an individual before he or she was moved to actually submit a complaint and that the Panel could not contact the complainant for more information. The Panel further noted that the complainant bore the burden of proof and did not consider that he/she had established his/her case on the balance of probabilities. The Panel therefore ruled no breach of Clauses 3.2, 7.2, 7.4, 9.1, 15.2, 15.4 and 15.9 of the Code.

Complaint received **3 February 2021**

Case completed **15 July 2021**